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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,707	01/19/2007	Osamu Ohara	3190-100	9479

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KILYK & BOWERSOX, P.L.L.C.
400 HOLIDAY COURT
SUITE 102
WARRENTON, VA 20186

EXAMINER	
KIM, ALEXANDER D	
ART UNIT	**PAPER NUMBER**
1656	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,707	OHARA ET AL.	
	Examiner	Art Unit	
	Alexander D. Kim	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. By virtue of a preliminary amendment filed on 09/28/2006, claims 4-5, 6-7, 12-13, 14-15, 17 and 19-23 have been amended. Claims 1-23 are pending in the instant case.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 4-9, 21 and 23, drawn to a polynucleotide shown by the nucleotide sequence set forth in SEQ ID NO: 1 or by the complementary nucleotide sequence, or a polynucleotide encoding a protein shown by the amino acid sequence set forth in SEQ ID NO: 2 or by the complementary nucleotide sequence; an agent comprising said polynucleotide for preventing and/or treating a stomach cancer; and a kit and comprising said polynucleotide, classified in class 536, subclass 23.1.

II. Claims 2 and 3, drawn to a polynucleotide shown by the nucleotide sequence set forth in SEQ ID NO: 3 or by the complementary nucleotide sequence, or a polynucleotide encoding a protein shown by the amino acid sequence set forth in SEQ ID NO: 4 or by the complementary nucleotide sequence, classified in class 536, subclass 23.1.

III. Claim 2, drawn to a polynucleotide shown by the nucleotide sequence set forth in SEQ ID NO: 5 or by the complementary nucleotide sequence, or a polynucleotide encoding a protein shown by the amino acid sequence set forth in SEQ ID NO: 6

or by the complementary nucleotide sequence, classified in class 536, subclass 23.1.

IV. Claims 10, 21 and 23, drawn to a protein shown by the amino acid sequence set forth in SEQ ID NO: 2; an agent comprising said polypeptide for preventing and/or treating a stomach cancer; and a kit comprising said polynucleotide, classified in class 530, subclass 350.

V. Claims 11 and 12, drawn to a protein shown by the amino acid sequence set forth in SEQ ID NO: 4, or a protein encoded by the polynucleotide according to claim 3, wherein the protein is not encoded from the complementary nucleotide of SEQ ID NO: 3, classified in class 530, subclass 350.

VI. Claims 11, drawn to a protein shown by the amino acid sequence set forth in SEQ ID NO: 6, classified in class 530, subclass 350.

VII. Claim 12, drawn to a protein encoded from a complementary nucleotide sequence of claim 3 including SEQ ID NO: 3, classified in class 530, subclass 350.

VIII. Claim 13, drawn to a method of producing the protein according to Claim 10, classified in class 435, subclass 69.1.

IX. Claims 14, 21 and 23, drawn to an antibody that recognizes the protein according to Claim 10; an agent comprising said antibody for preventing and/or treating a stomach cancer; and a kit containing said antibody thereof, classified in class 424, subclass 130.1.

X. Claims 15-18 and 22, drawn to a method of identifying a compound that inhibits the function of the protein according to Claim 10 and/or the expression of the polynucleotide or a complement thereof, comprising: detecting and determining the compound inhibits the function of the protein and/or the expression of the polynucleotide detection an usage of protein according to Claim 10; or using a protein, a polynucleotide encoding a protein of SEQ ID NO: 2, wherein the method does not involves antibody, classified in class 435, subclass 7.71.

XI. Claims 17-18 and 22, drawn to a method of identifying a compound that inhibits the function of the protein according to Claim 10 and/or the expression of the polynucleotide or a complement thereof, comprising using an antibody, classified in class 435, subclass 7.71.

XII. Claims 19-20, drawn to a method of determining whether a tissue specimen derived from a human stomach tissue, which is a tissue derived from a human stomach tumor or not comprising measuring an amount of expression of the polynucleotide, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Groups I-III are related by virtue of a polynucleotide of guanine nucleotide exchange factor. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See

MPEP § 806.05(j). In the instant case, the Groups I-III are not capable of use together, are mutually exclusive and are not obvious variants by virtue of distinct structure identified by different SEQ ID NOs. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Groups I-III and Groups IV-VII are related by virtue of a polypeptide encoded from a nucleotide of guanine nucleotide exchange factor. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the Groups I-III and Groups IV-VII are not capable of use together, are mutually exclusive and are not obvious variants. Although, the nucleic acid and the protein are related, Groups I-III and Groups IV-VII are distinct inventions from each other because they are wholly different in structure and function. A nucleic acid's structure is comprised of linear, contiguous nucleotides while a protein's structure comprised of linear, contiguous amino acids that fold into a specific three-dimensional structure; the nucleic acid's function is to encode a protein while a protein's function is variable, and in this case, biosynthesis of a penicillin and a cephalosporin. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Group I and Group VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the polynucleotide of Group I can be used in a process of DNA sequencing.

Groups I-VII and Group IX are related by virtue of a polynucleotide or polypeptide encoded from a nucleotide of guanine nucleotide exchange factor and antibody which recognize said proteins. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the Groups I-VII and Group IX are not capable of use together, are mutually exclusive and are not obvious variants because of following reasons: Antibodies are composed of amino acids in a specific contiguous and three-dimensional shape that is the basis for its recognition (binding) activity. By virtue of these distinct structures and functions, the nucleic acids and the antibodies are patentably distinct. While both polypeptides and antibodies are structurally related by virtue of their contiguous sequence of amino acids, they are distinct structures based on

their three-dimensional structures wherein proteins fold into a variety of structures and antibodies maintain a specific, Y-shape. Polypeptides are functionally distinct from antibodies because antibodies merely recognize a cognate peptide and polypeptides catalyze chemical reactions with a variety of substrates. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Group I and Group X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the polynucleotide of Group I can be used in a process of DNA sequencing reaction.

Groups I-VII and Group XI are related by virtue of a polynucleotide, encoded polypeptide, antibody of guanine nucleotide exchange factor or a tissue sample expressing said polynucleotide, or a method of using an antibody binding to a protein(s) thereof. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are

mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the Groups I-VII and Group XI are not capable of use together, are mutually exclusive and are not obvious variants because the method step of Group XI does not use or make the products of Groups I-VII. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Groups I-XI and Group XII are related by virtue of a polynucleotide, encoded polypeptide, antibody of guanine nucleotide exchange factor or a tissue sample expressing said polynucleotide, or a method of using a product thereof. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the Groups I-XI and Group XII are not capable of use together, are mutually exclusive and are not obvious variants because the method step of Group VIII does not use the products of Groups I-VII and IX or method steps of Groups VIII and X-XI. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Groups II-VII and Group VIII are related by virtue of a polynucleotide, encoded polypeptide of guanine nucleotide exchange factor and a method of making related

protein thereof. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the Groups II-VII and Group VIII are not capable of use together, are mutually exclusive and are not obvious variants because the method step of Group VIII makes the products of Group I and does not use or make products of Groups II-VII. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Groups II-III, V-VII and Group X are related by virtue of a polynucleotide, encoded polypeptide related to guanine nucleotide exchange factor and a method of using the product of Group I or IV which is protein or nucleotide of guanine nucleotide exchange factor. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the Groups II-III, V-VII and Group X are not capable of use together, are mutually exclusive and are not obvious variants because the method step of Group X does not use or make products of Groups II-III, V-VII.

Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Groups IV-VII are related by virtue of a polypeptide encoded from a nucleotide of guanine nucleotide exchange factor. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the Groups IV-VII are not capable of use together, are mutually exclusive and are not obvious variants by virtue of distinct structure identified by different SEQ ID NOs. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Group IV and Group X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the polypeptide of Group IV can be used in an N-terminal sequencing reaction.

Group VIII and Group IX are related by virtue of method of making a polypeptide of guanine nucleotide exchange factor and an antibody binding to said protein thereof. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the Group VIII and Group IX are not capable of use together, are mutually exclusive and are not obvious variants because the method step of Group VIII does not make or use the antibody of Group IX. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Groups VIII, X and XI are related by virtue of method of making a polypeptide of guanine nucleotide exchange factor, method of identifying a compound that inhibits said protein function and a method of using an antibody binding to said protein(s) thereof. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the method of Groups VIII, X and XI are not capable of use together, are mutually exclusive and are not obvious variants because the method

step of Groups VIII, X and XI are distinct from each other. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Group IX and Group X are related by virtue of method of an antibody binding to a polypeptide of guanine nucleotide exchange factor and method of identifying a compound that inhibits said protein function. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the method of Group IX and Group X are not capable of use together, are mutually exclusive and are not obvious variants because the method step of Group X does not require using the antibody of Group IX. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Group IX and Group XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product

as claimed can be used in a materially different process of using that product. For example, the antibody of Group IV comprising a polypeptide can be used in an N-terminal sequencing reaction.

Notice of Possible Rejoinder

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result**

in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander D. Kim whose telephone number is (571) 272-5266. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alexander Kim
2 January 2008

RICHARD HUTSON, PH.D.
PRIMARY EXAMINER